Notice of Allowability	Application No.	Applicant(s)	
	08/999,690	GUNZBURG ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *5/9/05*.

2. ☒ The allowed claim(s) is/are *9, 11, 12, 14, 15, 20, 21, 22, 26, 55, 60, 62-65, 70-72, 75, and 79*.

3. ☒ The drawings filed on *5/27/03* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
   1. ☒ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____.
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
   1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 5/23/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit: 1633

J.D.

DETAILED ACTION

This action is in response to the amendment filed May 9, 2005. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office action mailed on 11/8/2004 are withdrawn in view of the amendment, and the following Examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Daly on July 22, 2005.

The claims have been amended as follows:

9. (Currently amended) A recombinant retroviral vector system comprising:

a) A recombinant vector ~~which undergoes promoter conversion~~ comprising,

(i) a 5' long terminal repeat region comprising the structure U3-R-U5;

(ii) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group

consisting of: melittin, cecropin, magainin, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(iii) a 3' long terminal repeat region comprising a completely or partially deleted U3 region, wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell; and

(b) a packaging cell line harboring at least one retroviral construct coding for proteins required for said ~~retroviral~~ recombinant vector to be packaged.

11. (Currently amended) A retroviral particle produced by the recombinant retroviral vector system according to Claim 9 ~~after transfecting the packaging cell line with the retroviral vector~~.

14. (Currently amended) A method for introducing nucleotide sequences into an isolated cell population comprising infecting the cell population with the

retroviral particle according to Claim 11 ~~recombinant retroviruses produced by the recombinant retroviral vector system according to Claim 9~~.

20. (Currently amended) A mRNA of a retroviral provirus produced by infection of target cells with a recombinant retroviral particle from a recombinant retroviral vector system comprising:

(a) a recombinant vector ~~which undergoes promoter conversion~~ comprising,

(i) a 5' long terminal repeat region comprising the structure U3-R-U5;

(ii) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: melittin, cecropin, magainin, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(iii) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3~~

~~region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell; and

(b) a packaging cell line harboring at least one retroviral construct coding for proteins required for said ~~retroviral~~ recombinant vector to be packaged.

21. (Currently amended) A RNA produced by a recombinant retroviral vector ~~which undergoes promoter conversion~~ wherein said vector comprises,

(a) a 5' long terminal repeat region comprising the structure U3-R-U5;

(b) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: melittin, cecropin, magainin, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(c) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region~~

~~comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell.

26. (Currently amended) An isolated non-human host cell infected with a virion according to Claim 11.

27. (Canceled)

28. (Canceled)

30. (Canceled)

31. (Canceled)

34-40. (Canceled)

46-48. (Canceled)

52. (Canceled)

55. (Currently amended) A recombinant retroviral vector ~~which undergoes promoter conversion~~ comprising,

(a) a 5' long terminal repeat region comprising the structure U3-R-U5;

(b) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide

is selected from the group consisting of: cecropin, SB-37, Shiva-1, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(c) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell.

60. (Currently amended) A recombinant retroviral vector system comprising:

(a) a recombinant vector ~~which undergoes promoter conversion~~ comprising,

(i) a 5' long terminal repeat region comprising the structure U3-R-U5;

(ii) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: cecropin, a preform thereof, a preproform

thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(iii) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell.

(b) a packaging cell line harboring at least one retroviral construct coding for proteins required for said ~~retroviral~~ recombinant vector to be packaged.

61. (Canceled)

62. (Currently amended) A retroviral particle produced by the recombinant retroviral vector system according to Claim 60 ~~after transfecting the packaging cell line with the retroviral vector system~~.

65. (Currently amended) A method for introducing nucleotide sequences into an isolated cell population comprising infecting the cell population with the

retroviral particle according to claim 62 ~~recombinant retroviruses produced by the recombinant retroviral vector system according to Claim 60~~.

70. (Currently amended) A mRNA of a retroviral provirus produced by infection of target cells with a recombinant retroviral particle from a recombinant retroviral vector system comprising:

(a) a recombinant vector ~~which undergoes promoter conversion~~ comprising,

(i) a 5' long terminal repeat region comprising the structure U3-R-U5;

(ii) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: cecropin, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(iii) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker

sequence, resulting in at least one of said coding sequences becoming operatively linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell; and

(b) a packaging cell line harboring at least one retroviral construct coding for proteins required for said ~~retroviral~~ recombinant vector to be packaged.

71. (Currently amended) A RNA produced by a vector which ~~undergoes promoter conversion~~ wherein said vector comprises,

(a) a 5' long terminal repeat region comprising the structure U3-R-U5;

(b) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: cecropin, a preform thereof, a preproform thereof, a biologically active analogue thereof having antimicrobial activity, and a combination thereof; and

(c) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively

linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell.

75. (Currently amended) An isolated non-human host cell infected with a virion according to Claim 62.

79. (Currently amended) A recombinant retroviral vector ~~which undergoes promoter conversion~~ comprising,

(a) a 5' long terminal repeat region comprising the structure U3-R-U5;

(b) one or more coding sequences, said sequences being inserted into the body of the vector outside of the 5' and a 3' long terminal repeat regions, wherein at least one sequence encodes for at least one therapeutic antimicrobial peptide, wherein the antimicrobial peptide is selected from the group consisting of: melittin, cecropin, magainin, a preform thereof, a preproform thereof, a biologically active analogue thereof ~~having antimicrobial activity~~ having antimicrobial activity, and a combination thereof; and

(c) a 3' long terminal repeat region comprising a completely or partially deleted U3 region wherein said deleted U3 region is replaced by a polylinker sequence which comprises at least one unique restriction site and at least one insertion of a heterologous DNA fragment, ~~which can~~ wherein the heterologous DNA fragment regulates the expression of at least one of the coding sequences of said vector, and comprises ~~at least~~ one or more elements selected from the group consisting of: regulatory elements and promoters,

wherein after infection of a target cell, ~~said~~ the U3 region of said 5' long terminal repeat region is replaced by said ~~partially deleted U3 region comprising said heterologous DNA fragment~~ polylinker sequence, resulting in at least one of said coding sequences becoming operatively

linked to said heterologous DNA fragment and said heterologous DNA fragment regulating the expression of at least one of said coding sequences in said target cell.

Conclusion

Claims 9, 11, 12, 14, 15, 20, 21, 22, 26, 55, 60, 62-65, 70-72, 75, and 79 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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QJL
July 22, 2005